# EP-Tracer 510(k) Summary per 21CFR §807.92

**Submitter's information**

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Date: 12/27/2013

**Device/ classification name**

Device Name:
The EP-Tracer is a Class 2 device (product code DQK).

Classification/Common name:
- Programmable diagnostic computer, 21 CFR §870.1425,

The marketed device(s) to which substantial equivalence is claimed:
- Mennen Medical EMS-XL Cardiac Electrophysiology System, K071348

**Device description**

The EP-Tracer system is a computerized electrophysiology measurement system designed for both regular and experimental EP studies.

The EP-Tracer is comprised of these major components,

1. EP-Tracer hardware – Amplifier/stimulator
2. EP-Tracer Software – Software pre-installed

**Indications for use**

*"The EP-Tracer System is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record signals obtained during electrophysiological studies and related procedures.*

*"The system allows the user to monitor, display and record the signals. The system incorporates a stimulator intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart".*

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# Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

**Technological characteristics** The table below lists the technological characteristics for both the new and predicate devices

| Device Characteristic | Predicate Device Mennen EMS-XL | New Device EP-Tracer™ |
|---|---|---|
| **Amplifer Dimensions** (with integrated stimulator) WxDxH | 32 channels: 29x22x11 in cm<br>64 channels: 29x22x22 in cm | 38 channels: 28x27x7 in cm<br>70/102 channels: 28x27x12 in cm |
| **Environmental Specifications** | | |
| Temperature Operating | 0°C to +35°C | +10°C to +30°C |
| Temperature Transport/Storage | -15°C to +50°C | -29°C to +66°C |
| Humidity Operating | < 95 % rH at +35°C (non-condensing) | 20 - 80 % rH (non-condensing) |
| Humidity Transport/Storage | < 95 % rH at +35°C (non-condensing) | < 95 % rH (non-condensing) |
| **Power Specifications** | | |
| Power Requirements | 100 - 240 V AC, 50 - 60 Hz | Same |
| Power Input | +5 V, 0.0 - 0.2 A<br>+12 V, 0.0 - 0.3 A<br>-12V, 0.0 - 0.3 A | 38 channels:<br>+5 V, 0.3 A & +12 V, 0.9 A<br>70 channels:<br>+5 V, 0.3 A & +12 V, 1.5 A<br>102 channels:<br>+5 V, 0.3 A & +12 V, 2 A |
| **Design** | | |
| Sampling and Hold | Each channel sampled prior acquisition | Same |
| Sampling Rate | 1 kHz | Same |
| CMRR | > 100 dB | Same |
| Input Impedance | Typical 20 MΩ | Same |
| **Leakage Current.** | | |
| Patient Source | < 10 µA | Same |
| Patient Sink | < 10 µA | Same |
| Patient Sink (measured at patient leads under single fault conditions) | < 50 µA | Same |
| Chassis Leakage | < 100 µA | Same |
| **ECG Input** | | |
| Outputs | 12 lead ECG produced | Same |
| High Pass Filter | 0.05 Hz, 0.2 Hz, 40 Hz, 80 Hz | 0.05 Hz, 0.2 Hz |
| Low Pass Filter | 100 Hz | 150 Hz |
| RF Filtering | All inputs | Same |
| Gain | Between 0 and 255 mm/mV - continuous | Same |
| Saturation Recovery | < 1 sec | < 1 sec (manual reset) |
| Notch Filter | Power line (50/60 Hz) | Same |
| Dynamic Range | ±5 mV | Same |
| Baseline Correction | ±300 mV | Same |

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# EP-Tracer 510(k) Summary per 21CFR §807.92, Continued

**Technological characteristics** (continued)

| Device Characteristic | Predicate Device Mennen EMS-XL | New Device EP-Tracer™ |
|---|---|---|
| **Input/ Output** | | |
| Inputs 32/38 channels | 18 intracardiac channels, 2 pressure channels, 12 ECG channels | 20 intracardiac channels, 6 auxiliary channels, 12 ECG channels |
| Inputs 64/70 channels | 50 intracardiac channels, 2 pressure channels, 12 ECG channels | 52 intracardiac channels, 6 auxiliary channels, 12 ECG channels |
| Inputs 102 channels | N/A | 84 intracardiac channels, 6 auxiliary (pressure) channels, 12 ECG channels |
| Outputs | No outputs | Same |
| Switching | Each channel can be either bipolar or unipolar with manual switching | Same |
| High Pass Filter | 0.05 Hz, 0.2 Hz, 40 Hz, 80 Hz | Same |
| Low Pass Filter | 500 Hz | 350 Hz |
| RF Filtering | All inputs | Same |
| Gain | Between 0 and 255 mm/mV – continuous | Same |
| Saturation Recovery | < 1 s | < 1 s (manual reset) |
| Notch Filter | Power line (50/60 Hz) | Same |
| Dynamic Range | ±5 mV | Same |
| Baseline Correction | ±300 mV | Same |
| **Stimulator** (integrated into device) | | |
| Isolated Stimulus Channels | 2 | Same |
| **Pulse Amplitude** | | |
| Range | 0.1 - 25 mA into 1500 Ω load | 0 - 25.5 mA into 1000 Ω load |
| Increment | 0.1 ms | Same |
| Accuracy | ±0.15 ms | Same |
| **Pulse Duration** | | |
| Range | 0.1 - 9.9 ms | Same |
| Increment | 0.1 ms | Same |
| Accuracy | ±0.15 ms | Same |
| **Inter-Stimulus Interval (ISI)** | | |
| Range | 180 ms to 9990 ms +1 ms or ±0.1 % (whichever is larger) | 10 - 9999 ms |
| Range (Burst) | 30 ms to 9900 ms ±1 ms or ±0.1 % (whichever is larger) | 10 - 9999 ms |
| Increment | 10 ms | Same |

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# EP-Tracer 510(k) Summary per 21CFR §807.92, Continued

**Technological characteristics** (continued)

| Device Characteristic | Predicate Device Mennen EMS-XL | New Device EP-Tracer™ |
|---|---|---|
| **Sequential Delay (AV)** | | |
| Range | 11 - 250 ms | Same |
| Increment | 1 ms | Same |
| Programmed Protocols | Threshold panel key<br>SNRT panel key<br>Vent. Burst key<br>Atrial burst key<br>Vent. Overdrive key<br>Atrial overdrive key<br>Multi-Sx | Preprogrammed protocols:<br>BASIC 1 (induction)<br>BASIC 2 (termination)<br>BASIC 3 (backup)<br>ACUTE<br>Multi-Sx |
| Programmed Protocols | Pace<br>User defined protocol<br>User defined protocol | Pace<br>Automatic mode<br>Wenkebach mode<br>User defined protocols |
| Programmable Protocol Key | 5 | 10 |
| Number of Extra-Stimuli | 4 (S2 - S5) | 5 (S2 - S6) |
| **Sensing (ECG Synchronization)** | | |
| Automatic or Manual Trigger Setting – Sensitivity | Internal from any surface or intra-cardiac channel | Same |
| Automatic or Manual Trigger Setting – Trigger lockup (refractory time) | 5 - 5000 ms | Same |
| Automatic or Manual Trigger Setting – ECG Delay | 5 - 5000 ms | Same |
| Additional Outputs | No | Same |
| Power Source | Integrated with amplifier<br>+5 V, 0.0 - 0.2 A<br>+12 V, 0.0 - 0.3 A<br>-12 V, 0.0 - 0.3 A | Integrated with amplifier<br>38 channels:<br>+5 V, 0.3 A & +12 V, 0.9 A<br>70 channels:<br>+5 V, 0.3 A & +12 V, 1.5 A<br>102 channels:<br>−5 V, 0.3 A & −12 V, 2 A |
| | | |
| **Pacing Channels** | | |
| Isolated Channels | (i) atrial and<br>(ii) ventricular and<br>(iii) emergency fixed pace output to ventricle | (i) atrial and<br>(ii) ventricular and<br>(iii) emergency fixed pace output to atrium and ventricle |
| | | |
| Circuit Isolation | Compliant with IEC 60601-1, Class CF, 5 kV, common & differential mode | Same |

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# EP-Tracer 510(k) Summary per 21CFR §807.92, Continued

**Technological characteristics** (continued)

| Device Characteristic | Predicate Device Mennen EMS-XL | New Device EP-Tracer™ |
|---|---|---|
| **Computer Controlled Stimulus Pulses** | | |
| Current | 0.1 - 25.5 mA into 1500 Ω load 40 V | 0 - 25.5 mA into 1000 Ω load |
| Current Steps | 0.1 mA | Same |
| Accuracy | ±0.1 mA | Same |
| Pulse duration | Pulse width 0.1 - 9.9 ms, steps of 0.1 ms | Same |
| Accuracy | ±0.1 mA | Same |
| Load Impedance | 1500 Ω | 1000 Ω |
| Max. Output Voltage | 40 V | 25 V |
| **Inter-Stimulus Intervals** | | |
| S1 Range | 180 - 9990 ms (pace)<br>30 - 9990 ms (Burst pace) | 10 - 9999 ms |
| Stability | Quartz computer clock, ±30 parts per million at +25°C | Same |
| Extra-Stimuli | 4 (S2 - S5), independent | 5 (S2 - S6) |
| Coupling Interval | 30 - 9990 ms | Same |
| Accuracy | ±10 ms | Same |
| **Protocol Automation** | | |
| Auto decrement/ increment | Yes | Same |
| Backup Manually Controlled Stimulation | Use external backup stimulator | Same |
| Emergency Backup Pacing | Use external backup stimulator | Same |
| **Compliance with Standards** | | |
| Standards | UL 2601-1<br>IEC 60601-1-2 | EN 60601-1<br>EN 60601-1-2 |
| Device Directive | European Union Medical Device Directive (CE Marked) | Same |
| **Environmental/ Electrical Specifications** | | |
| Operating Temperature | 0°C to +35°C | +10°C to +30°C |
| Storage Temperature | -20°C to +65°C | -29°C to +66°C |
| Operating Humidity | 30 - 75 % rH (non-condensing) | 20 - 80 % rH (non-condensing) |
| Storage Humidity | 5 - 95 % rH (non-condensing) | < 95 % rH (non-condensing) |
| Max. Current Draw | 15 A/115 V, 7 A/230 V | Same |
| Chassis Leakage Current | < 100 µA | Same |

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# EP-Tracer 510(k) Summary per 21CFR §807.92, Continued

**Technological characteristics** (continued)

| Device Characteristic | Predicate Device Mennen EMS-XL | New Device EP-Tracer™ |
|---|---|---|
| **Advanced Features** | | |
| Display Ablation Parameters | Connection to RF ablation generator(s) | Same |
| **Certification** | | |
| MDD Device Class | Class IIb | Same |
| IEC 60601-1 | Certified | Same |
| EMC Compliance | Certified | Same |
| CE Marking | Certified CE 0473 | Certified CE 0459 |
| US Regulations | 510(k) cleared | Current submission |
| **System Dimensions** | | |
| WxDxH | Cart with display: 61x61x162 cm<br>Console with display: 90x85x125 cm | Customer Option<br>Mobile Cart: 100x80x170 cm<br>Mobile Desk: 125x80x150 cm<br>Control Desk: customer defined |

**Performance data**

Based upon the documentation presented in this 510(k) it has been demonstrated that the EP-Tracer System is safe and effective for its intended use.

The following lists the harmonized standards currently applicable to the EP-Tracer product:

- EN ISO 14971: 2012
- EN 980 : 2008
- EN 1041: 2008
- EN 60601-1 : 1998 + A1 : 1991 + A2 : 1995
- EN 60601-1-1 : 2000
- EN 60601-1-2 : 2001 + A1 : 2006
- EN 60601-1-4: 1996 + A1 : 1999
- IEC 60601-1-6: 2004
- EN 60601-2-34 : 2000
- IEC 62304 : 2006
- IEC 62366 : 2008
- ISO 13485: 2003 + C1 : 2009
- EN 60601-2-27

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 31, 2014

Cardiotek, B.V.
c/o Melissa Walker
Graematter, Inc.
1324 Clarkson Clayton Center #332
Ballwin, MO 63011

Re: K134044
Trade/Device Name: EP-Tracer system 38, EP-Tracer system 70, EP-Tracer system 102
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: January 20, 2014
Received: January 22, 2014

Dear Melissa Walker,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801) please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Appendix 2: Indications for Use Statement

**Statement**

The Indications for Use Statement:

510(k) Number: K_____

Device Name: EP-Tracer System

"The EP-Tracer System is an electrophysiology measurement system used to acquire, filter, digitize, amplify, display, and record signals obtained during electrophysiological studies and related procedures.

The system allows the user to monitor, display and record the signals. The system incorporates a stimulator intended to be used for diagnostic cardiac stimulation during electrophysiological testing of the heart".

Prescription Use __X___ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Linda J. Ricci -S